K002813

NOV 21 2000

510(k) Summary of Safety and Effectiveness

1. Manufacturer and Contact Information:

Manufacturer:	Nissho Nipro Corporation Ltd. 10/2 Moo 8, Bangnomko, Sena Ayutthaya, Thailand 13110
U. S. Distributor:	Nipro Medical Corporation 3150 N. W. 107 Avenue Miami, FL 33172
Contact Information:	Richard D. Bliss, Jr. Quality Systems Engineering 510 Stonemont Drive Weston, FL 33326 Telephone: (954) 385-1690 Fax: (954) 385-1256

2. Device Classification Name:

The Gastroenterology and Urology Devices Panel has classified Blood access device and accessories as Class II. Reference 21 CFR 876.5540.

3. Intended Use:

The Nipro® SafeTouch Safety Fistula Needle is intended for use as a blood access device for blood purification and for other treatments requiring an extracorporeal circuit or larger volumes of blood. Secondly, it is designed with an active sharp safety feature requiring physical action by the clinician in preventing needle stick incidents.

4. Device Description and Characteristics:

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) 1990.

The Nipro® SafeTouch Safety Fistula Needle includes arterial and venous fistula adapter consisting of flexible tube and needle with an active sharps safety feature (non-implanted blood access device) as described in 21 CFR 876.5540. The Nipro® Arterial and Venous Fistula Needle was previously described in detail as part of Premarket Notification cleared by FDA under K955182 on June 4, 1996.

The fistula needle included in this 510(k) is modified to include a sharps safety feature. The only modification made to the device is the addition of Acrylonitrylebutadiene Stylene (ABS) for the Safety Prevention system.

The sharps injury prevention system is connected between winged needle and polyvinyl chloride tubing and consists of three parts, the Safety Hub, Safety Stopper and Safety Protector. The needle is attached to the Safety Hub and is connected to the Safety Stopper. The Safety Protector then covers the Safety Hub.

The safety feature is easily operated through the release of a latch mechanism whereby the user slides a winged cover over the needle, as it is removed from the patient. Once the needle is covered, the safety cover latches into place. The safety feature presented in this document represents a substantially equivalent version of a different brand, which previously cleared FDA in K932074.

The Nipro® SafeTouch Safety Fistula Needle includes 2 basic types of design with clamps; fixed wing type (stationary) and turnable wing type (rotating) and will be offered in 96 configurations with options within it to include needle gauge, needle length, type of needle, and tubing length availability. A table with all the device configurations is included in Section 3 of this report.

The devices are packaged sterile and are labeled for single use only. There is no ability to clean and reuse these devices. They are restricted for sale by or on the order of a physician. The results of biocompatibility data support the equivalence of the predicate device and include sterility, safety, pyrogenicity, intracutaneous reactivity, systemic injection, hemolysis, implantation testing.

5. Substantial Equivalence

Nipro Medical Corporation considers the Nipro® SafeTouch Safety Fistula Needle to be substantially equivalent to the Medisystems ReadySet with MasterGuard with regard to intended use, materials, biocompatibility, and overall performance characteristics. The labeling is equivalent to the predicate device in intended use, components and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2000

Nipro Medical Corporation
C/O Mr. Richard D. Bliss
Quality Systems Engineering, Incorporated
510 Stonemont Drive
Weston, Florida 33326

Re: K002813
Trade Name: Nipro Safetouch Safety Fistula Needle
Regulatory Class: II and II
Product Code: FIE and FMI
Dated: September 1, 2000
Received: September 8, 2000

Dear Mr. Bliss:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Nipro® SafeTouch Safety Fistula Needle

Indications for Use:

The Nipro® SafeTouch Safety Fistula Needle is intended for use as a blood access device for blood purification and for other treatments requiring extracorporeal circuit. The Nipro® SafeTouch Safety Fistula Needle aids in the prevention of needle stick injuries. The compatibility of available configurations is the responsibility of the physician in charge.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **(Per 21 CFR 801.109)**

OR

Over-The-Counter-Use _ **(Optional Format 1-2-96)**

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002813